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PTO/SB/01 (12-97)

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| | | |
|---|-------------------------------|---------------|
| DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) <input checked="" type="checkbox"/> Declaration Submitted with Initial Filing OR <input type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required) | Attorney Docket Number | 1242/19/2 |
| | First Named Inventor | Summar et al. |
| | COMPLETE IF KNOWN | |
| | Application Number | |
| | Filing Date | Herewith |
| | Group Art Unit | |
| | Examiner Name | |

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**THERAPEUTIC METHODS RELATING TO CARBAMYL PHOSPHATE
SYNTHETASE I POLYMORPHISM**

the specification of which (Title of the Invention)

☒ is attached hereto
OR

☐ was filed on (MM/DD/YYYY) as United States Application Number or PCT International

Application Number and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 356(b) of any foreign application(s) for patent or inventor's certificate, or 356(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application, having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed | Certified Copy Attached? | |
|--|---------|-------------------------------------|--|--|--|
| | | | | YES | NO |
| | | | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

| Application Number(s) | Filing Date (MM/DD/YYYY) | <input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto. |
|-----------------------|--------------------------|--|
| | | |

[Page 1 of 2]

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

| U.S. Parent Application or PCT Parent Number | Parent Filing Date (MM/DD/YYYY) | Parent Patent Number (if applicable) |
|--|---------------------------------|--------------------------------------|
| 09/323,472 | June 1, 1999 | |

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02C attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

☐ Customer Number
OR

☒ Registered practitioner(s) name/registration number listed below

Place Customer
Number Bar Code
Label here

| Name | Registration Number | Name | Registration Number |
|----------------------|---------------------|-------------------|---------------------|
| Richard E. Jenkins | 28,428 | Jennifer L. Skord | 30,687 |
| Jeffrey L. Wilson | 36,058 | David P. Gloekler | 41,037 |
| Arles A. Taylor, Jr. | 39,395 | Gregory A. Hunt | 41,085 |

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label ☒ Correspondence address below

| | | | |
|---------|---|-----------|----------------|
| Name | Arles A. Taylor, Jr. | | |
| Address | JENKINS & WILSON, P.A. | | |
| Address | Suite 1400 University Tower, 3100 Tower Boulevard | | |
| City | Durham | State | NC |
| ZIP | 27707 | | |
| Country | USA | Telephone | (919) 493-8000 |
| Fax | (919) 419-0383 | | |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

| | |
|--|------------------------|
| Given Name (first and middle [if any]) | Family Name or Surname |
| Marshall L. | Summar |

| | | | | | |
|----------------------|-------------------|-------|----|---------|-------|
| Inventor's Signature | | | | Date | |
| Residence: City | Brentwood | State | TN | Country | USA |
| Citizenship | USA | | | | |
| Post Office Address | 513 Bel Air Place | | | | |
| Post Office Address | | | | | |
| City | Brentwood | State | TN | ZIP | 37207 |
| Country | USA | | | | |

☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

Please type a plus sign (+) inside this box → +

PTO/SB/02A (3-97)
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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 1

| | | | | | | | | |
|---|--|--------------------|-------|---|---------|-------|-------------|-----|
| Name of Additional Joint Inventor, if any: | | | | <input type="checkbox"/> A petition has been filed for this unsigned inventor | | | | |
| Given Name (first and middle [if any]) | | | | Family Name or Surname | | | | |
| Brian W. | | | | Christman | | | | |
| Inventor's Signature | | | | | Date | | | |
| Residence: City | | Nashville | State | TN | Country | USA | Citizenship | USA |
| Post Office Address | | 1713 Temple Avenue | | | | | | |
| Post Office Address | | | | | | | | |
| City | | Nashville | State | TN | ZIP | 37215 | Country | USA |
| Name of Additional Joint Inventor, if any: | | | | <input type="checkbox"/> A petition has been filed for this unsigned inventor | | | | |
| Given Name (first and middle [if any]) | | | | Family Name or Surname | | | | |
| | | | | | | | | |
| Inventor's Signature | | | | | Date | | | |
| Residence: City | | | State | | Country | | Citizenship | |
| Post Office Address | | | | | | | | |
| Post Office Address | | | | | | | | |
| City | | | State | | ZIP | | Country | |
| Name of Additional Joint Inventor, if any: | | | | <input type="checkbox"/> A petition has been filed for this unsigned inventor | | | | |
| Given Name (first and middle [if any]) | | | | Family Name or Surname | | | | |
| | | | | | | | | |
| Inventor's Signature | | | | | Date | | | |
| Residence: City | | | State | | Country | | Citizenship | |
| Post Office Address | | | | | | | | |
| Post Office Address | | | | | | | | |
| City | | | State | | ZIP | | Country | |

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Practitioner's Docket No. 1242/19

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: M.L. Summar et al.

Application No.: 09/323,472

Filed on: June 1, 1999

Title: HUMAN CARBAMYL PHOSPHATE SYNTHETASE I POLYMORPHISM
AND DIAGNOSTIC AND THERAPEUTIC METHODS RELATING
THERE TO

**STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(b))--NONPROFIT ORGANIZATION**

I hereby state that I am an official empowered to act on behalf of the nonprofit organization identified below:

Name of Nonprofit : Vanderbilt University
Address of Nonprofit : Office of Technology Transfer
1207-17th Avenue South, Suite 210
Nashville, Tennessee 37212

TYPE OF NONPROFIT ORGANIZATION

University or Other Institution of Higher Education.

I hereby state that the nonprofit organization identified above qualifies as a nonprofit organization, as defined in 37 CFR 1.9(e), for purposes of paying reduced fees to the United States Patent and Trademark Office under Sections 41(a) and (b) of Title 35, United States Code, with regard to the invention described in the specification filed herewith, with title as listed above.

I hereby state that rights under contract or law have been conveyed to, and remain with, the nonprofit organization, with regard to the above identified invention.

If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 C.F.R. 1.9(c), if that person made the invention, or by any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e)

Each such person, concern, or organization having any rights in the invention is listed below.

No such person, concern, or organization exists.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Larry R. Steranka, Ph.D.
Director
Office of Technology Transfer
Vanderbilt University
1207-17th Avenue South, Suite 210
Nashville, TN 37212

SIGNATURE Larry R. Steranka

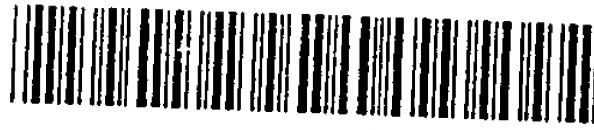
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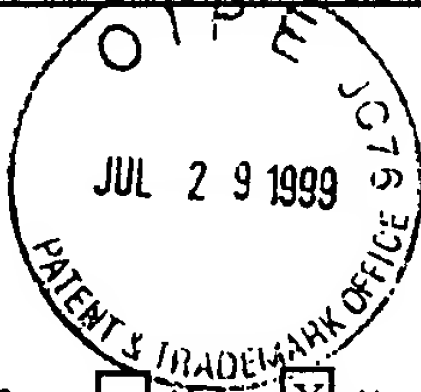
To the Honorable Commissioner of Patents and Trademarks

attached original documents or copy thereof.

1. Name of conveying party(ies):

Marshall L. Summar

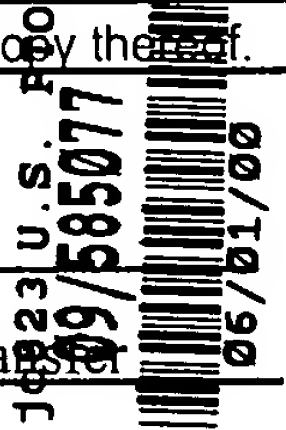
Brian W. Christman



2. Name and address of receiving party(ies):

Name: Vanderbilt University

Internal Address: Office of Technology Transfer



Additional name(s) of conveying party(ies) attached?

☐ Yes ☒ No

3. Nature of conveyance:

7.29.99

☒ Assignment

☐ Merger

☐ Security Agreement

☐ Change of Name

☐ Other

Street Address: 1207-17th Avenue South, Suite 210

City: Nashville State: TN ZIP: 37235

Execution Date: July 19, 1999

Additional name(s) & address(es) attached?

☐ Yes ☒ No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: _____

A. Patent Application No.(s)

09/323,472

B. Patent No.(s)

Additional numbers attached?

☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Arles A. Taylor, Jr.

Internal Address: Jenkins & Wilson, P.A.

University Tower, Suite 1400

Street Address: 3100 Tower Boulevard

City: Durham State: NC ZIP: 27707

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41) \$ 40.00

☒ Enclosed

☐ Authorized to be charged to deposit account

8. Deposit account number:

(Attach duplicate copy of this page if paying by deposit account)

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9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Arles A. Taylor, Jr.

Name of Person Signing

Arles A. Taylor, Jr.

Signature

July 27, 1999

Date

Total number of pages including cover sheet, attachments, and document: 4

Mail documents to be recorded with required cover sheet information to:
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Washington, D.C. 20231



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OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SEPTEMBER 30, 1999

PTAS

JENKINS & WILSON, P.A.
ARLES A. TAYLOR, JR.
UNIVERSITY TOWER, SUITE 1400
3100 TOWER BOULEVARD
DURHAM, NC 27707



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PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 07/29/1999

REEL/FRAME: 010129/0376
NUMBER OF PAGES: 4

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
SUMMAR, MARSHALL L.

DOC DATE: 07/19/1999

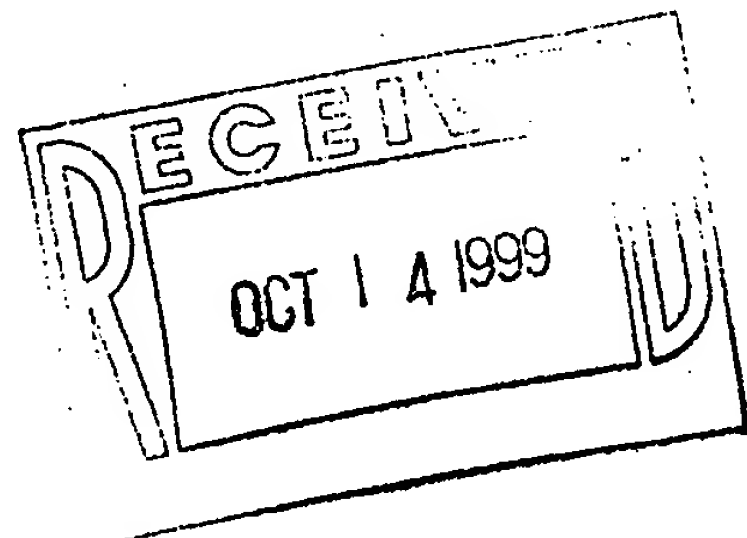
ASSIGNOR:
CHRISTMAN, BRIAN W.

DOC DATE: 07/19/1999

ASSIGNEE:
VANDERBILT UNIVERSITY
1207-17TH AVENUE SOUTH, SUITE 210
OFFICE OF TECHNOLOGY TRANSFER
NASHVILLE, TENNESSEE 38235

SERIAL NUMBER: 09323472
PATENT NUMBER:

FILING DATE: 06/01/1999
ISSUE DATE:



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010129/0376 PAGE 2

DOROTHY RILEY, PARALEGAL
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

PATENTASSIGNMENT

WHEREAS, Marshall L. Summar, of the City of Brentwood, State of Tennessee, and Brian W. Christman, of the City of Nashville, State of Tennessee (hereinafter "Assignors"), have invented certain new and useful improvements in HUMAN CARBAMYL PHOSPHATE SYNTHETASE I POLYMORPHISM AND DIAGNOSTIC AND THERAPEUTIC METHODS RELATING THERETO, for which we have made application for Letters Patent of the United States on June 1, 1999 as Application Serial No. 09/323,472.

AND, WHEREAS, Vanderbilt University, a non-profit organization located at Nashville, Tennessee, (hereinafter "Assignee"), is desirous of acquiring an interest therein.

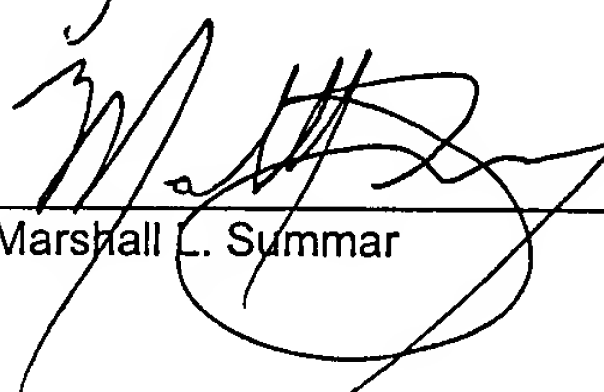
NOW, THEREFORE, To Whom It May Concern, be it known that for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignors have sold and by these presents do hereby sell, assign, transfer and convey unto the said Assignee, its successors and assigns, their entire right, title and interest in and to the said invention and application, and in and to any and all continuations, continuations-in-part, or divisions thereof, and in and to any and all Letters Patent of the United States of America and all foreign countries or reissues thereof which may be granted therefor or thereon, for the full end of the term for which said Letters Patent may be granted, together with their right to claim the priority of said application in all foreign countries in accordance with the International Convention, the same to be held and enjoyed by said Assignee, its successors and assigns, as fully and entirely as the same would have been held and enjoyed by Assignors if this assignment and sale had not been made.

Assignors hereby request that said Letters Patent be issued in accordance with this assignment.

Assignors further covenant and agree that, at the time of the execution and delivery of these presents, Assignors possess full title to the invention and application above-mentioned, and that they have the unencumbered right and authority to make this assignment.

Assignors further covenant and agree, and likewise bind their heirs, legal representatives and assigns, to promptly communicate to said Assignee or its representatives any facts known to them relating to said invention, to testify in any interference or legal proceedings involving said invention, to execute any additional papers which may be requested to confirm the right of the Assignee, its representatives, successors and assigns to secure patent or similar protection for the said invention in all countries and to vest in the Assignee complete title to the said invention and Letters Patent, without further compensation, but at the expense of said Assignee, its successors, assigns and other legal representatives.

Executed this 19 day of July, 1999.



Marshall L. Summar

Witnessed by:

Monica Blain 7/13/99
Name Date

Terri Bulby 7/20/99
Name Date

COPY

Executed this 13th day of July, 1999.



Brian W. Christman

Witnessed by:

James Elsner 7/13/99
Name Date

Monica Blain 7/13/99
Name Date

COPY